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EXAMINER	
UTAMA, ROBERT J	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/729,364	SZE ET AL.	
	Examiner	Art Unit	
	ROBERT J. UTAMA	3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-27 and 52-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-27, 52-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This office action is a response to the amendment and arguments received on 07/18/2008. The current status of the application is as follow: claim 1-2, 4-27, 52-58 are still pending. Claim 3, 28—51 have been cancelled.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1-2, 4-20, 21-27, 53 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 and 21 set forth a step for or a means for limitation language that is modified by a certain structure. In order for a claim to be considered as a mean for limitation, a claim must (A) use the phrase "means for " or "step for; (B) the "means for " or "step for " must be modified by functional language; and (C) the phrase "means for " or "step for " must not be modified by sufficient structure, material, or acts for achieving the specified function (see MPEP 2181). On claim 1 and 21 the phrase means for has been modified by sufficient structure and material (e.g ... mean comprising a second material, or means for selectivily modifying a model ... filler material to be added). Hence, it is not clear if claim 1-2, 4-20, 21-27 intend to invoke the means for limitation.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 58 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 58 set forth limitation of a kit and instruction for selectively adding a filler material that is not a disclosed in the specification as it was originally presented.

5. Claim 58 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 58 set forth limitation of a kit and instruction for selectively adding a filler material that is not a disclosed in the specification as it was originally presented.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 1-2, 4-27 and 52-58 rejected under 35 U.S.C. 103(a) as being unpatentable over Gain et al US 4,708,836, in view of NPL#1 and further in view of Cecchi 2003/0208101.

Claim 1: Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a second material comprising at least of a solid (see Gain col. 11:45-57). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second

material is readily distinguished in an ultrasound image of said model. The Gain reference provides a teaching of preventing tactile detection of a simulated patent skull sutures model, while enabling the simulated patent skull to be visually detected based upon an appearance of the simulated patent skull suture in an ultrasound image of said model (see col. 11:50-55 "skin")

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

The Cecchi reference provides a teaching of modifying of lowering or increasing the density of the material to control the echogenicity properties of the material. Therefore, it would have been obvious to one of ordinary skilled in the art to manipulate the density of the second material, as taught by Cecchi, because it would enable the head model to have the correct echogenic properties.

Claim 2: Gain provides a teaching for a medical simulator having a second material that fills opening in the first material (see col. 12:44-56). However, Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as

taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

Claim 4: While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that **t**he difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material.

The Cecchi reference provides a teaching of modifying of lowering or increasing the density of the material to control the echogenicity properties of the material. Therefore, it would have been obvious to one of ordinary skilled in the art to manipulate the density of the second material, as taught by Cecchi, because it would enable the head model to have the correct echogenic properties.

Claim 5 and 22: While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that **t**he difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark.

Claim 6: Gain provides a teaching where the model includes a scalp portion which include a scalp portion (see Gain FIG 15) and the scalp portion of the model is covered in layer of the second material, the second material covering at least a portion of the first material (see Gain col. 12:44-56). The limitation of "to prevent the simulated patent sutures from being identified tactilely" is being treated as an intended use limitation and currently not given patentable weight.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically

correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

Claim 7-9: The examiner contends that the reference of Gain and NPL #1 fails to show an ultrasound simulator with a patent suture that is filled with a mixture of starch and glue (**claim 7**). Similarly, the reference does not show the glue in the mixture to be a casein-based glue (**claim 8**) or a synthetic resin-based glue (**claim 9**). Instead, the combination of the Gain and NPL#1 reference used a mixture of oil and silicon (see col. col. 11:45-57).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model the sutures using a mixture of oil and silicon.or starch and glue mixtures. Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, the echogenicity of both materials are less than then solid portion of the skull. Therefore, it would have been prima facie obvious to modify Gain and NPL #1 to obtain the invention as specified in claim 7-9 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Gain and NPL#1.

Claim 10 and 11: Gain fails to provide a teaching of having a simulated patent skull sutures. The infant skull model (see NPL #1), shows a model substantially about the same size on human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, coronal, sagital and lambdoid sutures. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

However, the reference fails to show that the each of the sutures opening are beveled. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model to use beveled opening or any other types of opening (e.g.: flush opening). Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, since the type of opening would not matter in its echogenicity properties with respect to an ultrasound device or training.

Therefore, it would have been prima facie obvious to modify NPL #1 to obtain the invention as specified in claim 10 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of NPL #1.

Claim 12: Gain provides a teaching where the medical simulator comprised of at least one simulated fused skull sutures (see Gain FIG. 2).

Claim 13: *Gain provides a teaching where the medical simulator comprised of at least one simulated fused skull sutures made from a first material (see Gain col. 5:43-67 artificial cranium).*

Claim 15 and 55: The Gain reference fails to provide a teaching wherein the echogenicity of the third material is substantially similar to the first material, such that in an ultrasound image of the model, portions of the model comprising the first material are not readily distinguishable from portions of the model comprising the third material.

However, the Gain reference provides a teaching of having a patent suture filled with the first material (see FIG 2 between item 2 and 6). However, the same result can also be achieved by using the first material for the third material. Since they are made from the same material, the material should have similar echogenic properties.

Claim 18 and 19: Gain provides a teaching of an opaque layer configured to cover each of the simulated skull sutures and the scalp areas (see col. 12:44-56). The limitation of "so that a trainee cannot readily visually determine whether a specific skull sutures is patent or skull by inspecting the model" is being treated as an intended use limitation and currently not given patentable weight.

Claim 20: Gain provides in teaching where the head is utilized for the substantially life size model of a human head (see col. 2:7-14).

Claim 27: Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a second material comprising at least of a solid (see Gain col. 11:45-57). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material be readily distinguished in an ultrasound image of said model.
Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant. While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that **t**he difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark

8. Claim 14-17, 21-26 and 52-58 rejected under 35 U.S.C. 103(a) as being unpatentable over Gain et al US 4,708,836, in view of NPL#1, in view of Bergman US 5,609,485 further in view of Cecchi 2003/0208101.

Claim 14 and 25: The Gain reference fails to provide a teaching of each simulated fused skull suture comprised of an opening within said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model.

However, the Bergman reference provides a teaching of an opening within said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model (see Bergman 8:35-50). Therefore, it would have been obvious to one of ordinary skilled in the art at the time of invention of an opening within said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model, as taught by Bergman, in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies (see col. 2:1-5).

Claim 16-17 and 56: The Gain reference fail to provide the third material comprises a synthetic elastomer and the elastomer comprises of dimethyl siloxane, hydroxyl-terminated polymers and silica.

Instead the Gain reference provides a teaching of using epoxy resin instead of a synthetic elastomer and the elastomer comprises of dimethyl siloxane, hydroxyl-terminated polymers and silica as claimed.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use epoxy-resin, because Applicant has not disclosed that a synthetic elastomer and the elastomer comprises of dimethyl siloxane, hydroxyl-terminated polymers, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the epoxy resin and a synthetic elastomer, to perform equally well for the purpose of having the same echogenic properties as the first material.

Therefore, it would have been prima facie obvious to modify Gain to obtain the invention as specified in claim 16-17 and 56 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Gain.

Claim 21: Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a second material comprising at least of a solid (see Gain col. 11:45-57). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material is readily distinguished in an ultrasound image of said model. The Gain reference provides a teaching of preventing tactile detection of a simulated patent skull sutures model, while enabling the simulated patent skull to be visually detected based upon an appearance of

the simulated patent skull suture in an ultrasound image of said model (see col. 11:50-55 "skin")

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

The Cecchi reference provides a teaching of modifying of lowering or increasing the density of the material to control the echogenicity properties of the material. Therefore, it would have been obvious to one of ordinary skilled in the art to manipulate the density of the second material, as taught by Cecchi, because it would enable the head model to have the correct echogenic properties.

The Gain fails to provide a teaching of means for selectively modifying the model between training sessions by enabling a filler material to be added within at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material is added simulates a fused skull suture in an ultrasonic image, the model being modified between training sessions by removing the filler material from the at least one opening and adding the filler material within at least one other different opening. However, the Bergman provides a teahcing of selectively modifying the model between training sessions by enabling a filler material to be added within at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material is

added simulates a fused skull suture in an ultrasonic image, the model being modified between training sessions by removing the filler material from the at least one opening and adding the filler material within at least one other different opening (see col. 8:35-50). Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of selectively modifying the model between training sessions by enabling a filler material to be added within at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material is added simulates a fused skull suture in an ultrasonic image, the model being modified between training sessions by removing the filler material from the at least one opening and adding the filler material within at least one other different opening, as taught by Bergman, in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies (see col. 2:1-5).

Claim 22: While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that **t**he difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark.

C**laim 23 and 24:** While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that **t**he difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material.

The Cecchi reference provides a teaching of modifying of lowering or increasing the density of the material to control the echogenicity properties of the material. Therefore, it would have been obvious to one of ordinary skilled in the art to manipulate the density of the

second material, as taught by Cecchi, because it would enable the head model to have the correct echogenic properties.

Claim 25: The Gain reference fails to provide a teaching of each simulated fused skull suture comprised of an opening within said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model.

However, the Bergman reference provides a teaching of an opening within said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model (see Bergman 8:35-50). Therefore, it would have been obvious to one of ordinary skilled in the art at the time of invention of an opening within said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model, as taught by Bergman, in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies (see col. 2:1-5).

Claim 26: Gain fails to provide a teaching of having a simulated patent skull sutures. However, the infant skull model (see NPL #1), shows a model substantially about the same size on human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, coronal, sagital and lambdoid sutures. The reference also shows that the

sagital and metopic sutures are formed in a way that the opposites walls of the opening would meet in an end-to-end fashion. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

However, the reference fails to show that the each of the sutures opening are beveled. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model to use beveled opening or any other types of opening (e.g.: flush opening). Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, since the type of opening would not matter in its echogenicity properties with respect to an ultrasounic device or training.
Therefore, it would have been prima facie obvious to modify NPL #1 to obtain the invention as specified in claim 26 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of NPL #1.

Claim 52: Gain provides a teaching of medical simulator of substantially life-size model of human head (see col. 2:7-14) including two eyes, mouth, ears (see col. 11:17-30). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material be readily distinguished in an ultrasound image of said model.
Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically

correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

The Gain reference do not provide a teaching of skull suture that can be selectively modified to appear as a simulated skull suture and non suture portiosns fo the the model and from eachh simulated fused suture. However, the Bergman reference provides a teaching of a skull suture that can be selectively modified to appear as a simulated skull suture and non suture portiosns fo the the model and from eachh simulated fused suture (see col. 8:35-50). Therefore, it would have been obvious to one ordinary skilled in the art to include the feature of of skull suture that can be selectively modified to appear as a simulated skull suture and non suture portiosns fo the the model and from eachh simulated fused suture, as taught Bergman, in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies (see col. 2:1-5).

Claim 53: Gain provides a teaching of medical simulator of substantially life-size model of human head (see col. 2:7-14) including two eyes, mouth, ears (see col. 11:17-30). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The examiner takes the position that the difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

The Gain fails to provide a teaching of means for selectively modifying the model between training sessions by enabling a filler material to be added within at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material is added simulates a fused skull suture in an ultrasonic image, the model being modified between training sessions by removing the filler material from the at least one opening and adding the filler material within at least one other different opening. However, the Bergman provides a teahcing of selectively modifying the model between training sessions by enabling a filler material to be added within at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material is added simulates a fused skull suture in an ultrasonic image, the model being modified between training sessions by removing the filler material from the at least one opening and adding the filler material within at least one other different opening (see col. 8:35-50). Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of selectively modifying the model between training sessions by enabling a filler material to be added within at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that

each opening in which the filler material is added simulates a fused skull suture in an ultrasonic image, the model being modified between training sessions by removing the filler material from the at least one opening and adding the filler material within at least one other different opening, as taught by Bergman, in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies (see col. 2:1-5).

Claim 54 and 57: Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a second material comprising at least of a solid (see Gain col. 11:45-57). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The difference in density of the first material –epoxy resin- and the second material – oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material be readily distinguished in an ultrasound image of said model.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

The Cecchi reference provides a teaching of modifying of lowering or increasing the density of the material to control the echogenicity properties of the material. Therefore, it would have been obvious to one of ordinary skilled in the art to manipulate the density of the

second material, as taught by Cecchi, because it would enable the head model to have the correct echogenic properties.

The Gain reference fails to provide a teaching of each simulated fused skull suture comprised of an opening form in said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model.

The Gain reference provides a teaching of a third material being disposed within. However, the Bergman reference provides a teaching of a third material (see (see col. 8:35-50). Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of selectively modifying the model between training sessions by enabling a filler material to be added within at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material is added simulates a fused skull suture in an ultrasonic image, the model being modified between training sessions by removing the filler material from the at least one opening and adding the filler material within at least one other different opening, as taught by Bergman, in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies (see col. 2:1-5).

Response to Arguments

9. Applicant's arguments filed 07/18/2008 have been fully considered but they are not persuasive.

10. With respect to applicant's argument to claim 27, the applicant argues that the rejection under 35 U.S.C 103 is not valid since combination fail to include the feature of " ... at

least one simulated skull suture." The examiner respectfully disagrees. The base reference (Gain) provides a teaching of an adult looking skull model (see Gain FIG 2) with a fused skull sutures. The examiner takes the position that it is common knowledge that different skull bone in an adult human is characterized by fused skull sutures.

11. Applicant's arguments with respect to claim 1-2, 4-26, 52-58 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT J. UTAMA whose telephone number is (571)272-1676. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on (571)272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. U./
Examiner, Art Unit 3715

/XUAN M. THAI/
Supervisory Patent Examiner, Art Unit 3715